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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/718,770	11/22/2000	R. Terry Dunlay	97, 022-F3	5398

20306 7590 11/06/2006

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EXAMINER	
SMITH, CAROLYN L	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 11/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/718,770	DUNLAY ET AL.	
	Examiner	Art Unit	
	Carolyn L. Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-18 and 23-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-18 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09062006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission, filed 9/6/06, has been entered.

The information disclosure statement, filed 9/6/06, has been considered by the Examiner.

Claims herein under examination are 13-18 and 23-25.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-18 and 23-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

NEW MATTER

Applicant points to support for "subcellular" limitation on page 12 (lines 30-31), Figure 7, examples on page 12 (lines 1-31), Examples 1 and 2, and page 19 (lines 1-17). It is noted that written support is provided for the image analysis of two particular sub-cellular components, the nucleus and cytoplasm, but not for "subcellular" image data in general, which is broader in scope. Several limitations in instant claims 24 and 25 do not appear to have written support in the specification, claims, and/or drawings as originally filed: "perimeter", "height", "width", "ratio of fluorescent intensities", and "difference in fluorescent intensities". On page 12, line 4, written support is provided for "perimeter squared area", but not for "perimeter" which is broader in scope. On page 12, line 6, written support is provided for "height width ratio", but not for individual concepts of "height" and "width" which are broader in scope. On page 12, lines 14-15, written support is provided for "the ratio of the average fluorescent intensity of the cytoplasmic mask to the average fluorescent intensity within the cell nucleus for colors 2-4", but not for "ratio of fluorescent intensities" which is broader in scope. On page 12, lines 16-17, written support is provided for "the difference of the average fluorescent intensity of the cytoplasmic mask and the average fluorescent intensity within the cell nucleus for colors 2-4", but not for "differences in fluorescent intensities" which is broader in scope. Because the introduction of these limitations do not appear to have written support in the specification, claims, and/or drawings as originally filed, they are considered to be NEW MATTER. This rejection is maintained.

Applicants summarize the written description requirement (MPEP 2163). Applicants summarize the rejection regarding "subcellular" and point to support on page 12, lines 30-31, in

particular. It is noted that while this section provides support for two subcellular compartments, including cytoplasm and nucleus, it does not provide written support for "subcellular" image data in general, which is broader in scope that can encompass organelles, molecules, and other entities found in a cell. Applicants point to page 19 which states those skilled in the art will recognize a wide variety of distinct screens that can be developed. Applicants further point to support which states specific organelles which are reorganized in response to specific stimuli. However, neither of these sections provide adequate written support for "collecting subcellular image data" and "storing subcellular image data" (i.e. claim 13, step c) ii) and c) iii) which is different in scope. Applicants argue that the Examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the original disclosure a description of the invention defined by the claims. It is noted that the initial burden has been set forth by the stating what has written support and what doesn't have written support due to a broader scope of the amended limitation. As noted above, for example, page 19, states that "distinct screens can be developed" and states specific organelles which are reorganized in response to specific stimuli. Developing screens is not the same thing as "collecting subcellular image data from the cells in a well" (claim 13, step c) ii)) or "storing the subcellular image in the computer system database" (claim 13, step c) iii)). Mentioning "specific organelles can be reorganized in response to specific stimuli" does not mention or provide written support for "collecting" or "storing" subcellular image data. Subcellular image data is broader in scope to include organelles, molecules, and other entities that are not described by applicants in the originally filed disclosure.

Applicants argue that one of skill in the art would understand that determining "perimeter squared area" includes determining "perimeter". This statement is found unpersuasive as one skilled in the art could collect a perimeter squared area from the image data which does not necessarily include collecting the individual "perimeter" measurement from the image data which is broader in scope. Applicants argue that they were in possession of "calculating ... perimeter" because those skilled in the art know what "perimeter" is and the specification describes "perimeter squared area". This statement is found unpersuasive as "perimeter" and "perimeter squared area" are not the same thing. Furthermore, just because someone knows what something is does not automatically mean that an applicant has written support for that item. Applicants argue that the Examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the original disclosure a description of the invention defined by the claims. It is reiterated that "perimeter squared area" is not the same thing as "perimeter" and therefore differs in scope. Adequate written support is not achieved when such a difference in scope exists.

Applicants argue that one of skill in the art would understand that determining "height width ratio" includes determining "height". This statement is found unpersuasive as one skilled in the art could collect a height width ratio from the image data which does not necessarily include collecting the individual "height" measurement from the image data which is broader in scope. Applicants argue that they were in possession of "calculating ... height" because those skilled in the art know what "height" is and the specification describes "height width ratio". This statement is found unpersuasive as "height" and "height width ratio" are not the same thing. Furthermore, just because someone knows what something is does not automatically mean that

an applicant has written support for that item. Applicants argue that the Examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the original disclosure a description of the invention defined by the claims. It is reiterated that "height width ratio" is not the same thing as "height" and therefore differs in scope. Adequate written support is not achieved when such a difference in scope exists.

Applicants did not set forth arguments regarding "width" in their latest response, but previously argued that one of skill in the art would understand that determining "height width ratio" includes determining "width". This statement was previously found unpersuasive as one skilled in the art could collect a height width ratio from the image data which does not necessarily include collecting the individual "width" measurement from the image data which is broader in scope.

Applicants argue that the specification clearly provides explicit examples of using ratios of fluorescent intensities in the cytoplasm-nucleus translocation assays and translocation between cytoplasm and plasma membrane assays, including page 19, lines 3-15, of the specification. Applicants argue that it would therefore be clear to those of skill in the art that Applicants had possession of other translocation assays and that the ratios could be used in these other translocation assays. This statement is found unpersuasive as the written support in the specification focuses on the ratio of average fluorescent intensities that differs in scope. Applicants argue that page 19 states "Those skilled in the art will recognize a wide variety of distinct screens that can be developed based on the disclosure provided herein" which necessarily includes the determination of ratios of fluorescent intensities between organelles as exemplified by the disclosure on cytoplasm-nuclear translocation assays on page 12 of the

disclosure. This statement is found unpersuasive as pages 12 and 19 do not mention ratios that are part of the limitation for which Applicants are arguing written support. Applicants argue that the patent office does not present evidence or reasoning to explain why persons skilled in the art would not recognize that inventors were in possession of the invention. This statement is found unpersuasive as it has been documented what has written support and what does not. When limitations differ in scope or there is completely no mention of a limitation, then there is a lack of adequate written description. As previously described, it is acknowledged that written support is provided for "the ratio of the average fluorescent intensity of the cytoplasmic mask to the average fluorescent intensity within the cell nucleus for colors 2-4" (page 12, lines 14-15). The section on page 19, lines 3-15, of the specification does not provide adequate written support for "ratio of fluorescent intensities" as there is no mention of "ratios". Furthermore, the rejected limitation "ratio of fluorescent intensities" is broad and encompasses intensities which are not supported by the original disclosure.

Applicants argue that the specification clearly provides explicit examples of using differences in fluorescent intensities in the cytoplasm-nucleus translocation assays and translocation between cytoplasm and plasma membrane assays, including page 19, lines 3-15, of the specification. Applicants argue that it would therefore be clear to those of skill in the art that Applicants had possession of other translocation assays and that the differences could be used in these other translocation assays. This statement is found unpersuasive as the written support in the specification focuses on the difference of average fluorescent intensities which differs in scope. Applicants refer to a statement made in the previous office action stating "Applicants cite several passages on pages 12 and 19, but these passages fail to mention *differences*" and state

this is incorrect as the patent office has already admitted support for differences of fluorescent intensities between cytoplasm and nucleus. This statement is incorrect as Applicants have altered the statement from the previous office action from "ratios" to "differences". When the Examiner was mentioning pages 12 and 19 on page 5 of the previous office action it was addressing the "ratio of fluorescent intensities" NEW MATTER, not the "difference in fluorescent intensities" NEW MATTER. Applicants argue that those skilled in the art would recognize a wide variety of distinct screens that can be developed (page 19 of specification) which includes the determination of differences in fluorescent intensities between organelles. It is noted that the limitation "difference in fluorescent intensities" encompasses more than just intensities between organelles, such as other entities, which do not have adequate written support. Applicants argue that the patent office does not provide evidence or reasoning why persons skilled in the art would not recognize that inventors were in possession of the invention at the time the invention was filed. This statement is found unpersuasive as it has already been noted what has written support and what does not have written support due to a difference in scope. When an amended claim limitation differs in scope (i.e. encompasses different subject matter) from what was written in the originally filed disclosure, then a NEW MATTER issue arises as seen in the present case.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13-18 and 23-25 are rejected under 35 U.S.C. 102(e)(2) as being anticipated by Nova et al. (P/N 5,961,923).

This rejection is maintained.

Nova et al. disclose a method involving cell sorting assays, storage of matrices with memories on machine-readable media, and retrieving stored information (abstract) as recited in the preamble of instant claim 13. Nova et al. disclose the use of high throughput screening on microplate formats to screen a number of drug compounds and cell-based assays (col. 6, lines 7-19) which represents providing a microplate comprising cells and treating with a test compound, (as stated in instant claims 13, 15, and 16) wherein the matrices which are microplates containing 96, 384, or higher format wells with each well or selected wells including a memory device (col. 8, lines 30-36 and lines 63-67) as stated in step a) of instant claim 13. Nova et al. disclose computer systems and methods for recording, reading, or retrieving information in the data storage devices (col. 15 lines 60-67) which represent the computer system of instant claim 13.

Nova et al. disclose maintaining a database that includes all patient information for the sample as well as other aspects of the patient's file (col. 83, lines 9-20) which represents the computer system database, as stated in instant claim 13. Nova et al. disclose using memory devices that include the input/output of stored information for higher density memories (col. 13, lines 49-56) and software allowing the user to specify what chemical blocks are to be used, the number of steps, and pharmacophore names (col. 87, lines 39-51) as well as using user-entered compound names stored in a database (col. 88, lines 17-20) which represent storing input parameters used for screening in a database, as stated in step b) of instant claim 13 as well as software having instructions causing a computer to execute a method, as stated in instant claim 14. Nova et al. disclose individual particles can be identified by reserving certain memory locations for identification only, individual identification (col. 73, lines 1-11), as well as software providing archival capability for a 96-well format where individual wells can be selected (col. 88, lines 48-54) which represents selecting an individual well on the plate and storing information, as stated in step c)i) of instant claim 13 and microplate data, as stated in instant claim 17. Nova et al. disclose software reading one tag and encoded information including graphical displays, reports including progress (calculations) (col. 88, lines 16-34), searching for specific compounds with certain building blocks (feature data) including those already archived by displaying structure, archive location, microplate group name, number and well (col. 88, lines 55-62 and Figure 6), using fluorophors or other luminescent moieties, labeling molecules and biological particles, tagging molecules (abstract), tagging molecules such as antigens, antibodies, ligands, proteins, and nucleic acids and tagging by imprinting the matrix with identifying information (col. 4, lines 58-67 and col. 7, lines 6-15), using optical memories that rely on changes in chemical or physical

properties of molecules and storing information associated with each matrix including reaction detection (col. 7, lines 16-32 and lines 57-67), a photodetector and recording devices to detect fluorescent occurrence or other optical emission (col. 10, lines 6-23), and using bar codes associated with each well in a microtiter plate (col. 8, lines 60-67) which represents collecting, calculating, storing, and retrieving subcellular image data, cell feature data, well summary data, plate summary data in a database, as stated in steps i) through ix) of instant claim 13 as well as instant claim 17. Nova et al. disclose optical memory devices (OMD) and image acquisition from a camera that can be displayed to the system monitor including edges and peak signals as well as determining the average intensity of each cell (col. 9, line 18; col. 51, line 61 to col. 52, line 9 and lines 27-60; and Figure 31) which represents collecting image data, intensity analysis, and feature data of cells, as stated in instant claims 13 and 23-25. Nova et al. disclose repeating the steps for handling, writing, reading, and distributing the optical memory devices to the next process step (col. 54, lines 5-11 and Figure 18) which represents the repeating steps in step c) of instant claim 13. Nova et al. disclose other repeating screening protocols (col. 118, lines 35-36 and 54-57 and col. 128, lines 39-49). Nova et al. disclose recording devices including a photodetector to detect the occurrence of fluorescence or other optical emission and permitting data storage (col. 10, lines 6-23) which represents a computer system database that includes photographic image data, as stated in instant claim 18.

Thus, Nova et al. anticipate the instant invention.

Applicants summarize MPEP 2112, IV. Applicants argue that Nova et al. do not teach collecting subcellular image data from individual cells in the wells or any further steps as recited

in the claims. This statement is found unpersuasive as Nova et al. disclose the following limitations:

> Nova et al. disclose software reading one tag and encoded information including graphical displays, reports including progress (calculations) (col. 88, lines 16-34), searching for specific compounds with certain building blocks (feature data) including those already archived by displaying structure, archive location, microplate group name, number and well (col. 88, lines 55-62 and Figure 6), using fluorophors or other luminescent moieties, labeling molecules and biological particles, tagging molecules (abstract), tagging molecules such as antigens, antibodies, ligands, proteins, and nucleic acids and tagging by imprinting the matrix with identifying information (col. 4, lines 58-67 and col. 7, lines 6-15), using optical memories that rely on changes in chemical or physical properties of molecules and storing information associated with each matrix including reaction detection (col. 7, lines 16-32 and lines 57-67), a photodetector and recording devices to detect fluorescent occurrence or other optical emission (col. 10, lines 6-23), and using bar codes associated with each well in a microtiter plate (col. 8, lines 60-67) which represents collecting, calculating, storing, and retrieving subcellular image data, cell feature data, well summary data, plate summary data in a database, as stated in steps i) through ix) of instant claim 13 as well as instant claim 17. Nova et al. disclose optical memory devices (OMD) and image acquisition from a camera that can be displayed to the system monitor including edges and peak signals as well as determining the average intensity of each cell (col. 9, line 18; col. 51, line 61 to col. 52, line 9 and lines 27-60; and Figure 31) which represents collecting image data, intensity analysis, and feature data of cells, as stated in instant claims 13 and 23-25.

Applicants cite passages in Nova et al. (col. 51-52) and argue that this section does not refer to generating subcellular image data from cells in wells. This statement is found unpersuasive as instant claim 13 recites "collecting" not generating subcellular image data from the cells in wells. As discussed above, Nova et al. disclose fluorescently labeling molecules (i.e. proteins) and using photodetectors, recording devices to detect and store fluorescent emission data, and optical memories to store information regarding reaction detection with bar codes associated with each well in the microtiter plate as well as image acquisition which represents collecting subcellular image data from cells in the well. Subcellular image data has been broadly and reasonably interpreted to be anything involving subcellular and image data (i.e. data from

labeled proteins detected using a photodetector including bar codes associated with each well). Applicants summarize Nova et al. and argue that Nova et al. teach using total molecular landscape in combination with matrices to produce combinatorial libraries for the purpose of identification and tracking instead of the instant invention. This statement is found unpersuasive as Nova et al. teach the above purpose but also the limitations as stated in the instant claims (see 35 USC 102 rejection above). The purpose of Nova et al. is irrelevant as long as it discloses the limitations encompassed in the instant invention.

Applicants' arguments are deemed unpersuasive for the reasons given above.

Conclusion

No claim is allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform to the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811.

October 31, 2006

Carolyn Smith
Examiner
AU 1631